



Bioethical challenges emerging from new models of learning

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Perspective

Ranking 37th — Measuring the Performance of the U.S. Health Care System

Christopher J.L. Murray, M.D., D.Phil., and Julio Frenk, M.D., Ph.D., M.P.H.

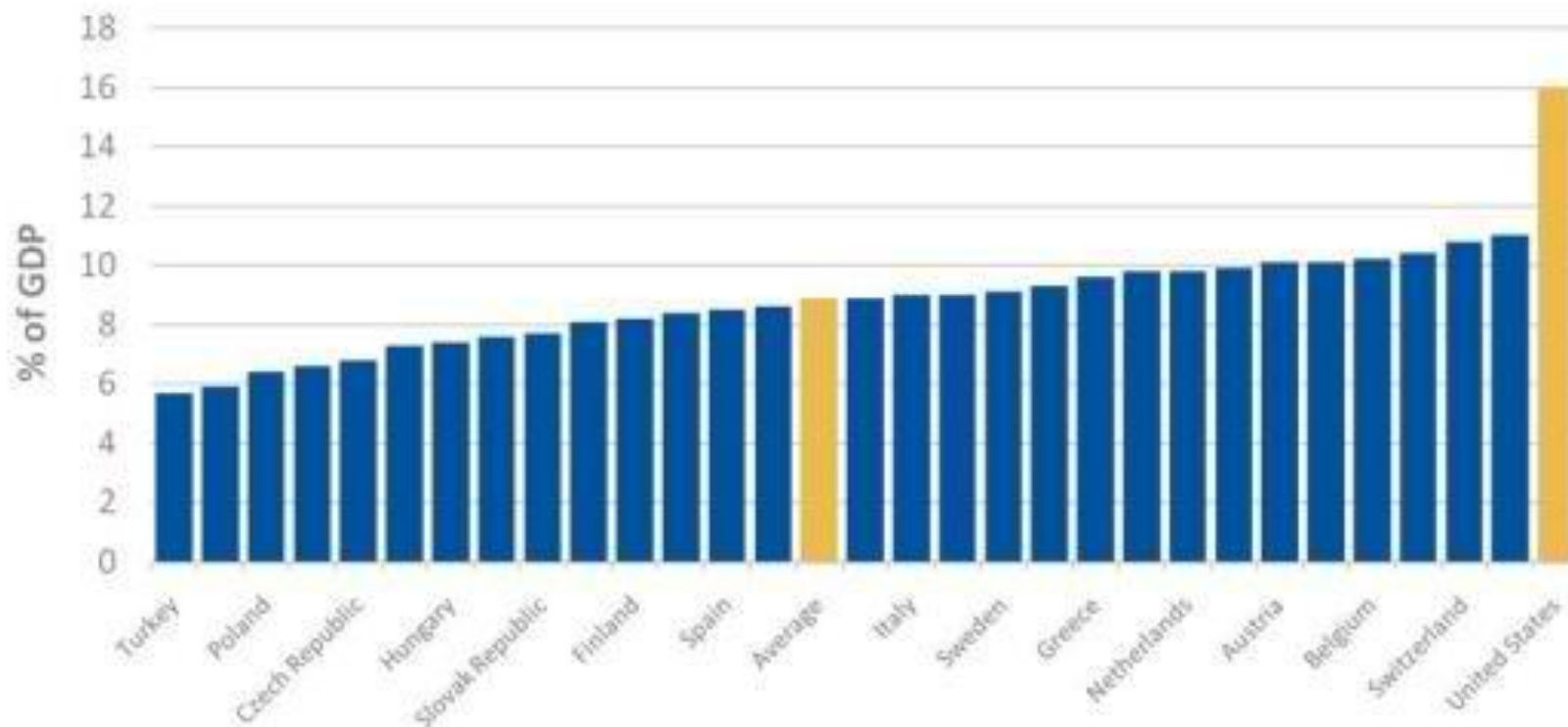
N Engl J Med 2010; 362:98-99 | January 14, 2010



Health Care Today

Health Care Spending as a Share of GDP

Total spending, 2007 or latest available



OECD Health Data 2009. France: Organisation for Economic Co-operation and Development and IRDES (Institute for Research and Information in Health Economics), 2009. (No authors given.)



Robert Wood Johnson Foundation



New models of learning required.

New models introduce new bioethical challenges.



Massachusetts Veterans Epidemiology Research and Information Center (MAVERIC)

- 130+ person **multi-disciplinary** research & development
 - Epidemiology (13 yrs)
 - Biospecimen repository (11 yrs)
 - Large scale clinical trials (8 yrs)
 - ISO 9001 Certified
 - Informatics (3.5 yrs)
- Goal: create a ***learning healthcare system*** within VA through application of research resources and methodologies to important clinical problems.



The Million Veteran Program





The VA's Unique Opportunity

- Learn how to keep Veterans healthy
- Maximize investment in genomic science
 - Genomic discovery requires large sample sizes
- Intramural research program
- Advance medical knowledge for society
 - 6 million “active” users
 - 20+ years of EMR data
- *83% of Veterans support genomic database
 - 71% would definitely or probably participate

*Kaufman et al. Veterans attitudes regarding a database for genomic research. Genetics in Med. (2009) 11, 329-337



The Million Veteran Program (MVP)

- The goal: 1m Veteran volunteers in 5-7 years
- Survey
 - 5 page baseline
 - 15 page comprehensive
- Blood sample
- Open consent & HIPAA authorization
- Access to the medical record
- Ability to re-contact



MVP Logistics

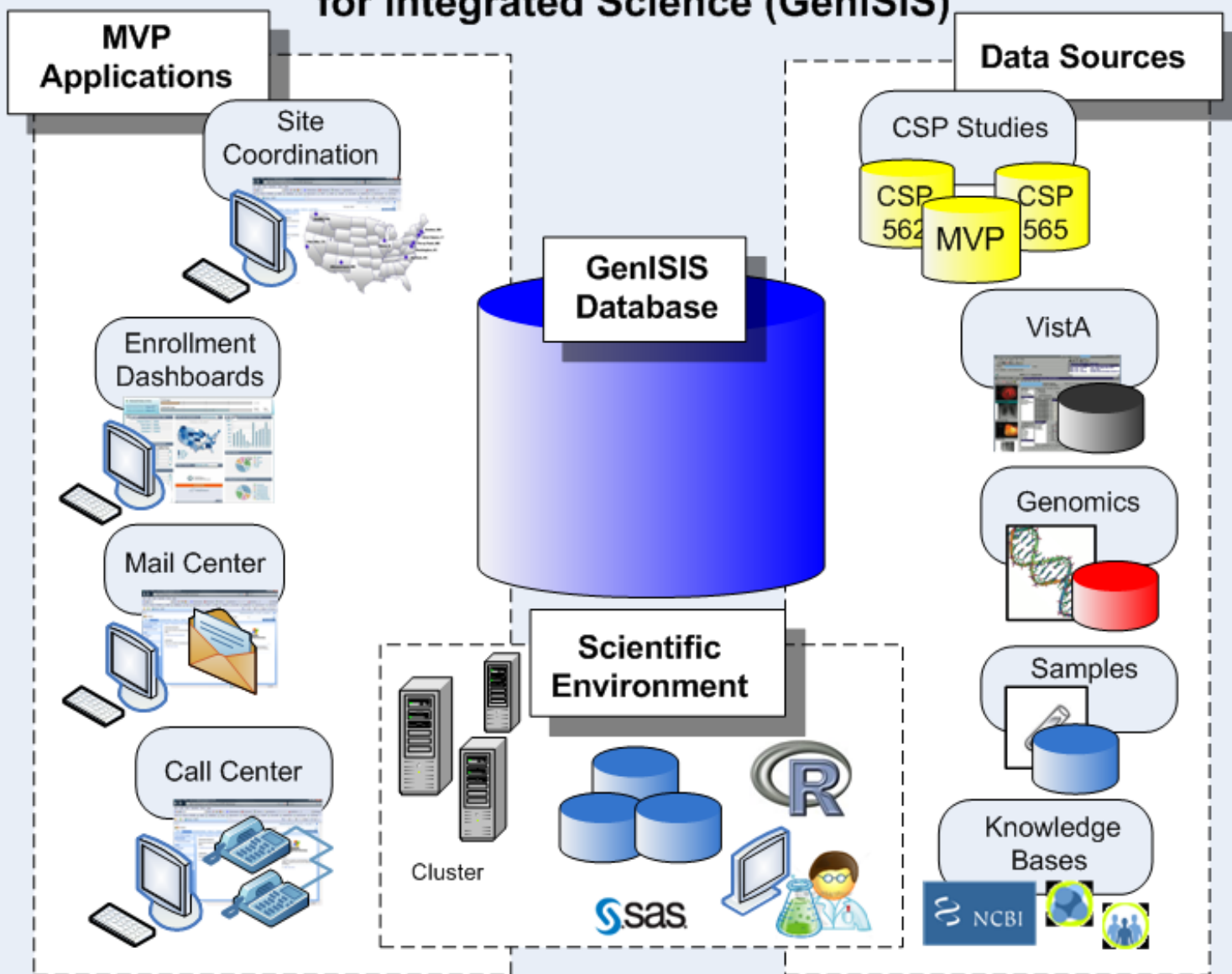
- 40 facilities enrolling
 - Scaling to 55
- Mail to every Veteran at enrolling clinics
- Survey & scheduling preferences by mail
- Consent & blood draw in person
- Call center for questions



Heavily Automated

- 20k invitations a week
- 7 different mail types
- 2000 calls per week (inbound + outbound)
- Dynamic form generation at sites
- 353 unique reports for 235 users
- Unified view of all interactions with Veteran

The Genomic Information System for Integrated Science (GenISIS)





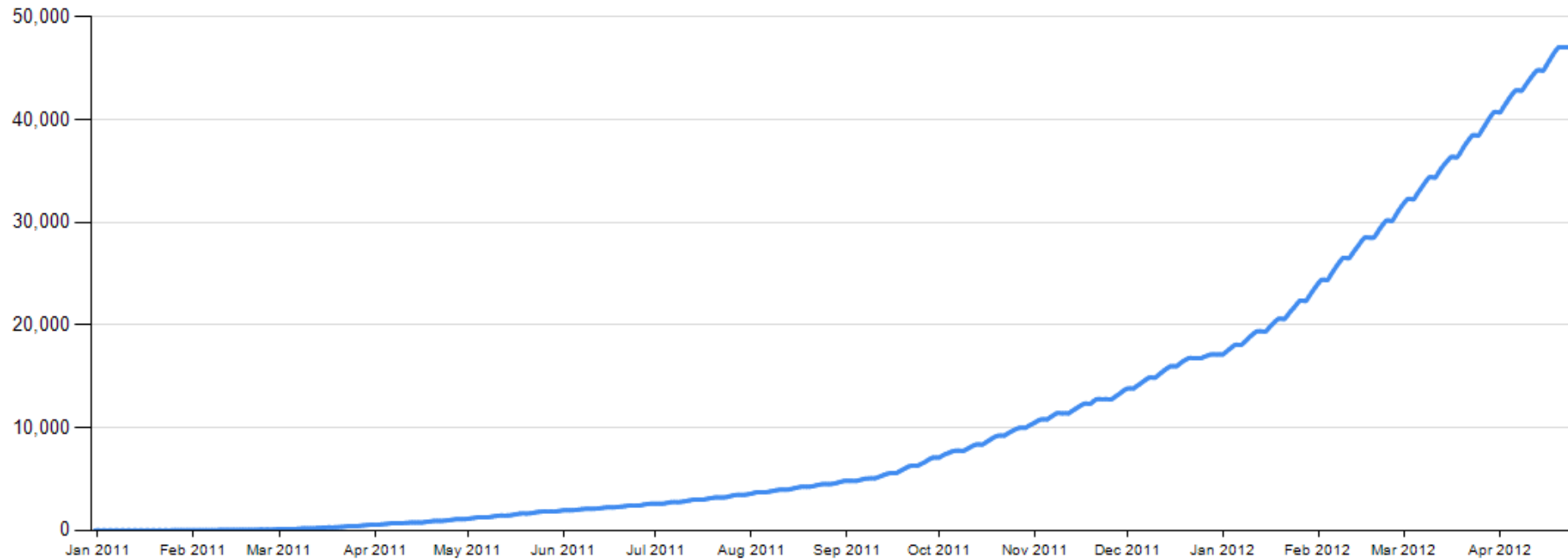
Secure Scientific Environment

- High performance computing environment
- Accessible to VA-credentialed investigators
- Data & analysis within the VA firewall
- Working on governance / access policies
 - *VA CSP DNA Bank founded May 1999

*Lavori et al. Principles, organization, and operation of a DNA bank for clinical trials: a Department of Veterans Affairs cooperative study. *Con Clin Trials* (2002) 23, 222-239



MVP Enrollment to Date





Bioethical Challenges

- “Informed” Open Consent?
- Emergent findings
 - What is our responsibility?
 - After disclosure?
- Generational information
- Access governance
 - Who can access?
- Responsibility to contribute data to public sources?



Point of Care Research Program



Current models of science do not support clinical effectiveness research

- RCTs too expensive
 - Millions of \$ & several years to answer few questions
 - Questions of generalizability
- Observational studies suffer from bias
 - Confounding by indication
 - Data quality issues

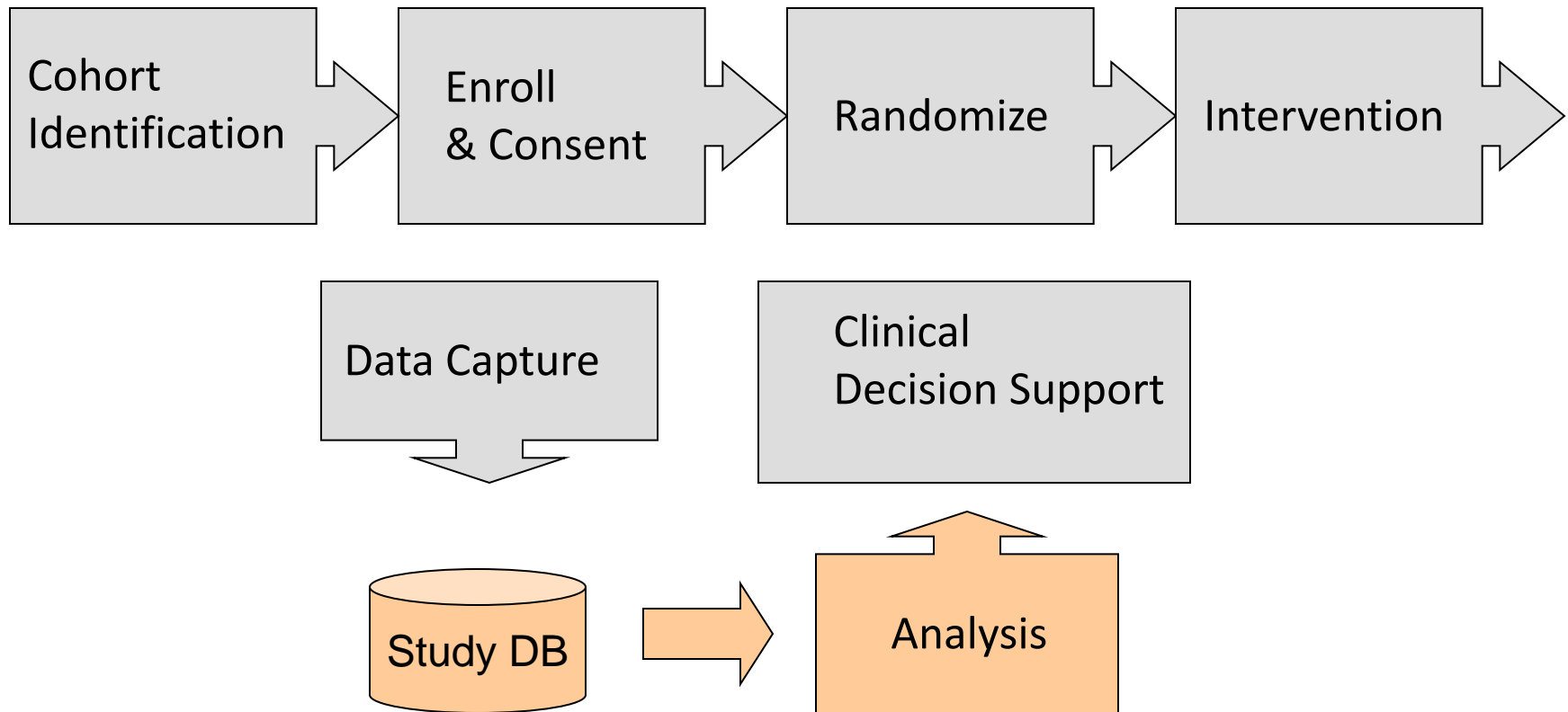


Point of Care Clinical Trial

- A clinical trial with a **substantial portion of its operations conducted by clinical staff** in the course of providing patient/subject's routine clinical care and where the choice of treatment is between two "equivalent" options



Care providers using EMR



Study team using traditional scientific tools



First Point of Care Clinical Trial

- Boston VA initiative
- Insulin protocol
 - Sliding scale insulin regimen
 - Weight based insulin regimen
- Both regimens are approved and in use at VA Boston
- No published data comparing outcomes
- *Consent obtained via a study nurse



Endocrine Medication Menu

Done

Diabetes Medications

Insulin Options:

- 1. No preference for insulin regimen. Consider enrollment in an inpatient study of Weight Based vs. Sliding Scale protocols.**
To choose option 1 ****Click HERE****
- 2. Weight Based insulin protocol.**
Weight Based Insulin protocol ****Click HERE****
- 3. Sliding Scale or other inpatient insulin regimen.**
Other Inpatient Insulin Orders ****Click HERE****

Portland Protocol (ICU Patients)
Portland Protocol ****Click HERE****

Oral Hypoglycemics
Oral Diabetes Medications Menu ****Click HERE****

Thyroid Medications
Thyroid Medications Menu ****Click HERE****

Steroids (under construction)



Recruitment Summary

Recruitment	N (%)
Number of Eligible Patients	129
No response from clinician	17
Clinician refusal	21
Patients who declined participation	4
Patients not enrolled for administrative reasons	4
Number of Patients Enrolled	83 (64.3%)
Patients Randomized	75
Patients Consented to Chart Review	8
Clinician Participation	
Clinician-Initiated Consults	37 (28.7%)



POC-CT Bioethical Considerations

- What level of consent is appropriate?
 - How best to obtain it?
 - Program or study-dependent?
- The system will be engaged in continual improvement
 - Is the clinician “engaged in research”?
- Consider:
 - Quality improvement – consent waived
 - Cluster randomization – consent waived



MVP Leadership Team

- MVP co-PIs: Michael Gaziano & John Concato
- MVP Director: Colleen Shannon
- MAVERIC Exec Director: Louis Fiore
- VA Office of Research and Development
 - Joel Kupersmith
 - Timothy O’Leary
 - Ronald Przygodzki
 - Sumitra Muralidhar



VA POOCR Leadership Team

- Principal Investigators: Louis Fiore and Philip Lavori
- Co-Investigators: Mary Brophy, James Kaufman, Mike Gaziano
- Informatics: Leonard D'Avolio and Chester Conrad
- CPRS Engineers: Gus O'Neil and Tom Sabin
- Ethics and Informed Consent: John Hermos
- Content Expert: Stephen Swartz
- Data Management: Ryan Ferguson, Galena Sokolovskaya
- Statisticians: Robert Lew, Gheorghe Doros
- VA Office of Research and Development
 - Joel Kupersmith
 - Timothy O'Leary
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